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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,269	10/16/2003	John Gavin MacDonald	KCX-841 (19233)	9988
22827	7590	06/07/2010		
DORITY & MANNING, P.A. POST OFFICE BOX 1449 GREENVILLE, SC 29602-1449			EXAMINER ALSTRUM ACEVEDO, JAMES HENRY	
			ART UNIT	PAPER NUMBER
			1616	
			MAIL DATE	DELIVERY MODE
			06/07/2010	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# **Advisory Action** **Before the Filing of an Appeal Brief**

## **Application No.**

10/687,269

## **Applicant(s)**

MACDONALD ET AL.

## **Examiner**

JAMES H. ALSTRUM  
ACEVEDO

## **Art Unit**

1616

**—The MAILING DATE of this communication appears on the cover sheet with the correspondence address —**

THE REPLY FILED 03 June 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## **NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

## **AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because:  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 1, 4-10, 12, 14, 17, 20-26, 28-29, and 31-44.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

## **AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

## **REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

/Johann R. Richter/  
Supervisory Patent Examiner, Art Unit 1616

6/06/10

Continuation of 11, does NOT place the application in condition for allowance because: Applicants' after final response does not include any claim amendments. Applicants traverse the rejections of record under 35 USC § 103(a) based on Persson (WO 00/76558) in view of several secondary references (i.e. Tratnyek, Horan, Baker, Patel, Karapasha, Takaoka, and Stoddart, respectively) and as evidenced by the June 1995 BOC Gases MSDS by arguing that (1) there is no incentive or motivation to combine the cited references to arrive at Applicants' claimed invention; (2) the suggested combination allegedly fails to disclose all the limitations of Applicants' independent claims; and (3) Applicants interpret the office action as improperly taking official notice.

The Examiner respectfully disagrees with Applicants' traversal arguments. Regarding (3), the Office has not taken official notice. Thus, Applicants' assertion to this effect is factually incorrect and Applicants' arguments about the alleged taking of official notice are unfounded. Applicants appear to interpret the variation of the concentration or amount of a particular component in a composition as being something not within the skill of the ordinary skilled artisan, yet Applicants provide no objective evidence that the ordinary skilled artisan would be unable to understand how to vary the amount of a component in a composition or would lack the skill to do so. This position is not credible, as evidenced by the fact that the prior art teaches ranges and/or different amounts of different components. For example, Tratnyek explicitly teaches two different amounts that are suitable for Michler's hydrol. Thus, Applicants' implied argument that it is somehow beyond the skill of the ordinary artisan to modify the amount of a component in a composition or article is without merit and statements that this ability is within the skill of the ordinary artisan is NOT taking of official notice. Applicants are reminded that ordinary skilled artisan's are not automatons, so they can think and are quite capable of making modifications that are routine in the art, such as changing the amount of a component in a composition or article.

Regarding (2), Applicants' arguments rest on the notion that if a reference does not contain Applicants' recited limitations verbatim that somehow the reference is incapable to teach or suggest said limitation. Such a notion is not supported by any case law and Applicants have not cited any case law indicating that a limitation in an obviousness rejection can only properly be rejected or addressed with verbatim language. As explained in the prior paragraph, the modification of the amount of a component in a composition is well within the skill of the ordinary artisan and is routinely practiced. Thus, the combined prior art provides ample basis for one to infer the modification of the amount of a component in an article or a composition is within the skill of the ordinary artisan and to utilize common sense to explain this conclusion.

Regarding (1), Applicants attack the references individually. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Contrary to Applicants' assertions, the combined prior art references demonstrate that visual indicators that change color based on the indicator's local environment (e.g. due to changes in pH or interaction with particular compounds) are well known in the art, especially, the visual indicator's recited in Applicants' claims. Furthermore, the use of a visual indicator as a visual indicator (i.e. it's art recognized utility) is *prima facie* obvious. The fact that the references relied upon may articulate different specific situations where a visual indicator is useful does not detract from the notion that the visual indicators are still functioning according to their art-recognized use. Applicants also argue that it is axiomatic for a visual indication system used to indicate when sterilization is incomplete to indicate anything less than complete sterilization. This statement ignores the reasoning given in the office action for using different concentrations (see page 7 of the final office action mailed on March 4, 2010). Applicants have not rebutted the reasoning provided on page 7 of the final office action nor addressed. Thus, Applicants are understood to concede that said reasoning is valid, because Applicants did not address it.

For the aforementioned reasons, the rejections of record in the March 4, 2010 final office action are maintained.